Docket No: S63.2-4944-US04



#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Burmeister et al.

**Application No.:** 

09/427,291

Filed:

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For:

IMPROVED TISSUE SUPPORTING

**DEVICES** 

Examiner:

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Group Art Unit: -

3738

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Washington, D.C. 20231

#### Letter Supplementing and Amending Request for Interference

This paper supplements and amends the request for interference provided in the Preliminary Amendment filed October 26, 1999.

In the Preliminary Amendment of October 26, 1999, Applicants requested an interference with U.S. Patent No. 5,827,321 to Roubin et al. (the "Roubin '321 patent"), filed February, 7, 1997 under U.S. Application No. 08/797,814, on the basis of a single Count corresponding exactly to claim 1 of the Roubin '321 patent and to Applicants' claim 22. Applicants' claims 22-32 and 34 were identified as corresponding to the Count and the Roubin '321 patent's claims 1-7, 9, 13-16 and 20 were also identified as corresponding to the Count. By this letter, Applicants supplement and amend the previous letter thereby requesting additional claims be designated as corresponding to the Count. A formal request to be accorded benefit of the priority filing dates of applications claimed in this application is also being made herein. Information submitted pursuant to the requirements of 37 C.F.R. § 41.202(a) is also specifically identified herein.

#### I. Request to be Accorded Benefit of Prior Applications

Applicants hereby formally request that in the declaration of the interference they be accorded benefit of the filing date of parent U.S. Application No. 08/737,492 to Burmeister et al.

(the "Burmeister '492 application"), which is a § 371 U.S. National Stage application of PCT/US95/06228, filed May 18, 1995 (the "PCT application"). Applicants are entitled to the May 18, 1995 PCT application filing date of the Burmeister '492 application based on copendency and the assertion of priority right under 35 U.S.C. § 120 in the present application and in the Burmeister '492 application. The disclosure of the present application, the parent Burmeister '492 application, and the corresponding PCT application are identical. Therefore, Applicants can establish a constructive reduction to practice of the claimed invention at least as early as May 18, 1995.

Applicants also formally request that in the declaration of the interference they be accorded benefit of the May 19, 1994 filing date of U.S. Application No. 08/246,320 (the "Burmeister '320 application"), since the PCT application was filed within one year of the May 19, 1994 filing date of the Burmeister '320 application and since Applicants have asserted the priority right thereto in the PCT application, the parent Burmeister '492 application, and the present application.

This request is supplemented with a Petition submitted herewith to correct the USPTO file for the Burmeister '320 application to restore three missing pages of drawings. Therefore, Applicants can establish a constructive reduction to practice of the claimed invention at least as early as the May 19, 1994 filing date of the Burmeister '320 application.

## II. Patents and Applications with which Applicants seek an Interference (37 C.F.R. § 41.202(a)(1)

For Burmeister et al.:

09/427,291, filed May 26, 1999, pending "the present application" or "the Burmeister '291 application."

#### For Roubin et al.:

08/797,814, filed February 7, 1997, patented **U.S. 5,827,321** (the "Roubin '321 patent"); 09/179,021 filed on October 26, 1998, patented **U.S. 6,106,548** (the "Roubin '548 patent");

09/641,121 filed on August 17, 2000, patented U.S. 6,475,236 (the "Roubin '236 patent"); and

10/892,718 filed on July 16, 2004, pending, published as **U.S. 2004-0267350** (the "Roubin '718 application").

#### III. Identification of Other Related Applications

For Applicants:

08/246,320, filed May 19, 1994 (the "Burmeister '320 application"), abandoned; 08/737,492, PCT filing date May 18, 1995, patented as **U.S. 6,582,461** (the "Burmeister '492 application" or the "Burmeister '461 patent"); 09/172,590, filed October 14, 1998, patented as **U.S. 6,451,052** (the "Burmeister '590 application" or the "Burmeister '052 patent"); and 10/443,231, filed May 21, 2003, pending, published as **U.S. 2003-0208263** (the "Burmeister '231 application").

#### For Roubin et al.:

10/283,957 filed on October 30, 2002, patented **U.S. 6,764,506** (the "Roubin '506 patent")

#### IV. Clarification of a Previous Statement

On page 4 of the Appeal Brief filed April 9, 2004 in the present application, the undersigned made the following statement:

In the present case it is noted that the immediate parent application, Application No. 08/737,492, corresponds exactly to the application as filed, except for the preliminary amendment which introduced claims 22-34. That is, the abstract, the entire specification, claims 1-21, and all of the drawing figures of the present application are found in the parent application, 08/737,492, which is a §371 national stage application of PCT/US95/06228, filed May 18, 1995.

While this statement is true because the content of the present application and the PCT application correspond exactly, line and page numbers of the present application and the PCT application differ due to reprinting. Citations to line and page numbers in the Appeal Brief were to the location in the present application. In the Written Description and Constructive Reduction to Practice tables that follow, page and line number citations are provided separately for each of the present application, PCT application as published in WO 95/31945 (the "Burmeister WO publication") and the Burmeister '320 application.

#### V. Proposed Count (37 C.F.R. § 41.202(a)(2))

One Count is proposed:

1. A stent comprising:

a plurality of annular elements, each annular element having a compressed state and an expanded state, wherein each annular element has a longitudinal dimension which is smaller in the radially expanded state than in the compressed state; and

connecting members connecting adjacent annular elements;

wherein the annular elements and connecting members are made of Nitinol, with each connecting member preset with an elasticity which causes the connecting member to elongate longitudinally when the annular elements are in their expanded state to compensate for the smaller longitudinal dimension of the annular elements in the expanded state.

#### VI. Amended Designation of Claims (37 C.F.R. § 41.202(a)(2))

Applicants request that the interference be declared with the following designation of claims corresponding to the Count.

Roubin et al.: U.S. 5,827,321, claims 1-54;

U.S. 6,106,548, claims 1-12; U.S. 6,475,236, claims 1-25; and

U.S. Application No. 10/892,718, claim 1.

Burmeister et al.: U.S. Application No. 09/427,291, claims 22-32 and 34.

#### VII. Detailed Basis for Designation of Claims (37 C.F.R. § 41.202(a)(2))

In the following analysis, each claim is analyzed from the perspective of the Count being taken as prior art to the claim. Either alone or taken together with the Count, the relevant prior art to Roubin et al., that describe all of the claim elements of the Roubin et al. claims sought to be designated as corresponding to the Count, is at least:

WO 95/31945, published November 30, 1995 (the "Burmeister WO publication"), the PCT publication of Applicants' immediate parent application, the PCT application, the U.S. National Stage of which is the Burmeister '461 patent. The publication date of WO 95/31945 is more than one year before Roubin et al.'s earliest filing date and so it is a prior art reference under 35 U.S.C. § 102(b);

U.S. 5,643,312 to Fischell et al., filed February 25, 1994 (the "Fischell '312 patent"), is prior art to Roubin et al. under 35 U.S.C. § 102(e);

- U.S. 5,749,825 to Fischell et al., filed September 18, 1996 (the "Fischell '825 patent"), is prior art to Roubin et al. under 35 U.S.C. § 102(e);
- US 5,609,627 to Goicoechea et al., filed October 4, 1994 (the "Goicoechea '627 patent"), is prior art to Roubin et al. under 35 U.S.C. § 102(e); and
- US 5,954,743 to Jang, filed March 26, 1997 (the "Jang '743 patent"), claiming priority to, and incorporating therein by reference, Provisional Application No. 60/017,484, filed April 26, 1996, (the "Jang '484 application') is prior art to Roubin et al. under 35 U.S.C. § 102(e) <sup>1</sup>. The incorporated Jang '484 application discloses the features of the Jang '743 patent that are relied on to show that the claims of the Roubin et al. patents and patent applications correspond to the Count and are thus entitled to the priority date of the Provisional Application. In this respect, the relevant features disclosed by Jang will be cited by reference to the Jang '484 Provisional Application.

#### Roubin et al. US 5,827,321

#### Claim 1:

A stent comprising:

a plurality of annular elements, each annular element having a compressed state and an expanded state, wherein each annular element has a longitudinal dimension which is smaller in the radially expanded state than in the compressed state; and

connecting members connecting adjacent annular elements;

wherein the annular elements and connecting members are made of Nitinol, with each connecting member preset with an elasticity which causes the connecting member to elongate longitudinally when the annular elements are in their expanded state to compensate for the smaller longitudinal dimension of the annular elements in the expanded state.

Claim 1 is the Count so it is properly designated as corresponding to the Count.

#### Claims 2-7, 9, 13-15, and 20:

- 2. The stent of claim 1, wherein each annular element comprises a plurality of alternating struts and apices connected to each other to form a substantially annular configuration.
- 3. The stent of claim 2, wherein the connecting members are connected to the apices of the adjacent annular members.

<sup>&</sup>lt;sup>1</sup> Jang Application 60/017,484 is also incorporated by reference into US Patent Nos.6,770,088, 6,409,761, 6,241,760, 6,152,957, 6,039,756, and 5,922,021. If for any reason incorporation into US 5,954,743 is not effective to render Application 60/017,484 a §102(e) reference against Roubin et al., these patents are submitted in the alternative as having the same disclosure and being effective from the filing date of Application 60/017,484 for the subject matter thereof.

- 4. The stent of claim 2, wherein the plurality of struts comprises left and right struts, with each pair of left and right struts connected to each other at an apex.
- 5. The stent of claim 2, wherein each strut has a longitudinal dimensional which is smaller when the annular elements are in the expanded state than in the compressed state.
- 6. The stent of claim 2, wherein each strut has a longitudinal dimensional which is larger when the annular elements are in the compressed state than in the expanded state.
- 7. The stent of claim 2, wherein at least one of the annular elements is closed such that the plurality of alternating struts and apices are connected to each other to form a closed annular element.
- 9. The stent of claim 1, wherein at least of connecting member has a plurality of alternating segments.
- 13. The stent of claim 9, wherein the at least one connecting member has a plurality of alternating and angled straight segments.
- 14. The stent of claim 1, wherein each connecting member has a larger longitudinal dimension when each annular element is in the expanded state than in the compressed state to compensate for the smaller longitudinal dimension of the annular element in the expanded state.
- 15. The stent of claim 1, wherein each connecting member has a smaller longitudinal dimension when each annular element is in the compressed state than in the expanded state to compensate for the larger longitudinal dimension of the annular element in the compressed state.
- 20. The stent of claim 1, wherein the annular elements and connecting members define an alternating longitudinal pattern of annular elements and connecting members.

Claims 2-7, 9, 13-15, and 20 are the additional claims of the Roubin '321 patent which Applicants have copied as application claims 23-32 and 34, respectively. These Roubin '321 patent claims and Applicants' corresponding claims 23-32 and 34, correspond to the Count and depend from a claim corresponding to the Count. Applicants, as senior party, are *prima facie* entitled to the subject matter of these claims.

Applicants are also entitled to have the issue of the unpatentability and priority of Roubin et al. claims 2-7, 9, 13-15, and 20, as well as the claims that follow, resolved in the interference. Therefore, Applicants request that claims 2-

7, 9, 13-15 and 20 of the Roubin '321 patent be designated as corresponding to the Count. Applicants also request that all of the following claims of other Roubin et al. patents and applications be designated as corresponding to the Count and be included in the interference. Those claims are:

U.S. 5,827,321, claims 8, 10-12, 16-19 and 21-54; U.S. 6,106,548, claims 1-12; U.S. 6,475,236, claims 1-25; and U.S. Application No. 10/892,718, claim 1.

In discussing features of the various claims, Applicants refer to figures contained in several publications that are prior art to Roubin et al. Applicants have attached, as Appendix A, copies of those figures for the convenience of the Examiner, including the Burmeister WO publication Figs. 6, 8a-8b, 9a-9b, 10a-10d, and 11a-11b, the Fishcell '312 patent Fig. 8, the Fischell '825 patent Fig. 5, the Goicoechea '627 patent Figs. 1a, 2a, 13-14, 23, and 32-34, and the Jang '484 application Fig. 8. Some of the figures were annotated to point out particular features.

#### Additional claims from Roubin et al. U.S. 5,827,321

Claim 8: The stent of claim 7, wherein at least one of the annular elements are open such that the plurality of alternating struts and apices are not connected at at least one location.

The Burmeister WO publication, which is the corresponding PCT application of the present application, discloses the Count and further discloses that *omitting portions* in a stent can increase flexibility, and also illustrates omitted connectors in Figs. 9a-9b and 10a-10d. Burmeister expressly teaches omitting portions other than the connecting elements to improve flexibility. Page 12, lines 13-16. Deleting other elements, such as the annular elements or the alternating struts of Figs. 11a and 11b, results in a plurality of alternating struts and apices not connected at at least one location.

Moreover, the features of claim 8 are found in the bifurcated stents of the Goicoechea '627 patent (e.g. Fig. 1a showing omitted annular elements) and the

Fischell '825 patent (Figs 1 and 5 showing alternating struts and apices not connected to allow blood flow through the stent at a bifurcation).

Claim 10: The stent of claim 9, wherein the connecting member has a plurality of alternating curved segments defining alternating top and bottom curved apices.

The features of claim 9, which was copied in the present application as claim 29, are described in the Burmeister WO publication, Figs. 11a and 11b. A detailed description of the features of claim 9 in Figs. 11a and 11b, as well as the features of the other claims copied in the present application, is discussed herein in the Written Description Claim Chart in Section X that follows.

The additional features of claim 10 are disclosed in the Fischell '312 patent. Fig. 8 shows undulating longitudinals that include alternating curved segments defining alternating top and bottom curved apices. The undulating longitudinals bend more easily during insertion into a vessel thereby increasing the flexibility of the stent. Col. 3, lines 38-40 and 45-49.

Claim 11: The stent of claim 10, wherein each of the plurality of alternating curved segments has an amplitude and a wavelength, and wherein the plurality of alternating curved segments have a smaller amplitude and a greater wavelength when the annular elements are in the expanded state than when the annular elements are in the compressed state.

The features of claim are 10 discussed above. The additional features of claim 11 are disclosed in the Burmeister WO Publication and the Fischell '312 patent. Burmeister Figs. 11a and 11b show connectors having alternating segments with an amplitude that decreases and a wavelength that increases when expanded. Fischell Fig. 8 shows undulating longitudinals/connectors with curved segments that have an amplitude and a wavelength. Modified with the Fischell connector for improved flexibility, the Burmeister connector will have curved segments that also have an amplitude that will decrease and a wavelength that will increase when the stent is in the expanded state as compared to their dimensions in the compressed state.

Claim 12: The stent of claim 9, wherein the at least one connecting member has a plurality of alternating curved and straight segments.

The features of claim 9 are discussed above in connection with claim 10. The additional features of claim 12 are disclosed in the Fischell '312 patent, Fig. 8. The undulating longitudinals shown in Fig. 8 have a plurality of alternating curved and straight segments which provide the benefit of increased flexibility. Col. 3, lines 45-49.

Claim 16: The stent of claim 1, wherein the stent has a plurality of segments along its length, each segment assuming a different diameter when the annular elements are in their expanded state.

The Count is disclosed in the Burmeister WO publication. The additional features of claim 16 are disclosed in the Jang '484 application. Jang identifies the desirability for a tapered stent at page 3, line 36 - page 4, line 5, and discloses at least one embodiment of such a stent at Fig. 8, page 16, lines 33-34, and page 24, line 10 - page 27, line 31. In Jang's Fig. 8, the segments G, H, I, J have different lengths relative to each other and to the lengths of segments A-F. This difference produces different diameters for each segment F-J when the stent is expanded. The stent can be made of Nitinol, page 12, line 16, and may be self-expanding, page 12, line 20. Differential segment lengths along a stent of the Count accommodate body vessel taper.

In addition, the additional features of claim 16 are disclosed in the Fischell '825 patent. Fischell provides dual diameter stents, col. 1, lines 34-37, to accommodate non-uniform diameter blood vessels, col. 1, lines 13-17.

Furthermore, the additional features of claim 16 are disclosed in the Goicoechea '627 patent. Goicoechea Fig. 1A shows a bifurcated stent which has two segments (12, 16) that expand to different diameters and a segment (14) that is tapered.

Claim 17: The stent of claim 16, wherein the stent has a tapered configuration in which the diameter of the stent gradually changes from one segment to another segment.

The features of claim 16 are discussed above. The additional features of claim 17 are disclosed in the Jang '484 application. Jang discloses a stent that

tapers gradually to match the naturally tapering anatomy of a blood vessel to account for blood vessel taper. Page 24, lines 25-28.

Claim 18: The stent of claim 16, wherein the stent has a stepped configuration in which the diameter of the stent transitions abruptly from one segment to another segment.

The features of claim 16 are discussed above. The additional features of claim 18 are disclosed in the Goicoechea '627 patent. Goicoechea Fig. 1A shows a transition segment (14) that is short relative to segments (12 and 16) and is therefore "abrupt."

Claim 19: The stent of claim 1, further in combination with a biocompatible graft covering.

The Count is disclosed in the Burmeister WO publication. The additional features of claim 19 are disclosed in the Goicoechea '627 patent. Goicoechea teaches using biocompatible graft covering materials with stents. Col. 10, lines 30-39. The graft material may therefore be used with the stents illustrated in Figs. 11a and 11b of Burmeister to allow the Burmeister stent to be used for deployment in an aortic bifurcation, or more generally, for deployment in an aneurismatic vascular segment. Goicoechea further teaches that the graft material may be used to prevent embolic particles from being introduced into the blood stream. Col. 5, lines 54-63.

Claim 21: A stent having a first segment and a second segment, with each segment having a diameter and comprising:

a plurality of annular elements, each annular element having a compressed state and an expanded state;

at least one connecting member connecting adjacent annular elements;

a plurality of apertures defined by adjacent annular elements and connecting members, each aperture having a size and a geometric configuration;

with the first and second segments having substantially the same diameter in the compressed state; and

wherein the apertures of the first and second segments have different sizes but substantially the same geometric configuration when the first and second segments are in the expanded state.

The features of claim 21 are disclosed in the Count taken with the Burmeister WO publication and with the Goicoechea '627 patent. The Count recites a stent having a plurality of annular elements, compressed and expanded

states, and a plurality of connecting members connecting adjacent annular elements. A stent as in Figs. 11a and 11b of Burmeister has apertures defined by adjacent annular elements and connecting members.

Goicoechea discloses a stent having two segments (12, 18) which have substantially the same diameters in a compressed state, as shown in Fig. 13, but different sizes when expanded, as shown in Fig. 14. In the expanded state the apertures of the first and second segments have different sizes but substantially the same geometric configuration. This configuration facilitates using the stent for deployment at a bifurcation or to provide different levels of support for diseased and non-diseased sections of the blood vessel as shown in Fig. 14. These features are also illustrated in Figs. 1A, 2A, 23, and 32-34.

Claim 22: The stent of claim 21, wherein each annular element comprises a plurality of alternating struts and apices connected to each other to form a substantially annular configuration, and wherein the connecting members are connected to the apices of the adjacent annular members, with the apertures defined by the adjacent struts and connecting members.

The features of claim 21 are discussed above. The additional features of claim 22 are shown in Burmeister Figs. 11a and 11b.

Claim 23: The stent of claim 21, wherein each segment of the stent assumes a different diameter when the annular elements are in their expanded state.

The features of claim 21 are discussed above. The additional features of claim 23 are disclosed in the bifurcated stents of the Goicoechea '627 patent and the Fischell '825 patent, and in the tapered stent of the Jang '484 application, as discussed above in connection with claim 16.

Claim 24: The stent of claim 23, wherein the stent has a tapered configuration in which the diameter of the stent gradually changes from one segment to another segment.

The features of claim 23 are discussed above. The additional features of claim 24 are disclosed in the tapered stent of the Jang '484 application, as discussed above in connection with claim 17.

Claim 25: The stent of claim 23, wherein the stent has a stepped configuration in which the diameter of the stent transitions abruptly from one segment to another segment.

The features of claim 23 are discussed above. The additional features of claim 25 are disclosed in the bifurcated stents of the Goicoechea '627 patent as discussed above in connection with claim 18.

Claim 26: The stent of claim 21, wherein the at least one connecting member has a plurality of alternating segments.

> The features of claim 21 are discussed above. The additional features of claim 26 are shown in the Burmeister WO publication, Figs. 11a and 11b.

Claim 27: The stent of claim 26, wherein the at least one connecting member has a plurality of alternating curved segments defining alternating top and bottom curved apices.

> The features of claim 26 are discussed above. The additional features of claim 27 are disclosed in the Fischell '312 patent, as discussed above in connection with claim 10.

The stent of claim 27, wherein each of the plurality of alternating curved segments has an Claim 28: amplitude and a wavelength, and wherein the plurality of alternating curved segments have a smaller amplitude and a greater wavelength when the annular elements are in the expanded state than when the annular elements are in the compressed state.

> The features of claim 27 are discussed above. The additional features of claim 28 are disclosed in the Fischell '312 patent, as discussed above in connection with claim 11.

Claim 29: The stent of claim 26, wherein the at least one connecting member has a plurality of alternating curved and straight segments.

> The features of claim 26 are discussed above. The additional features of claim 29 are disclosed in the Fischell '312 patent, as discussed above in connection with claim 12.

Claim 30: The stent of claim 26, wherein the at least one connecting member has a plurality of alternating and angled straight segments.

> The features of claim 26 are discussed above. The additional features of claim 30 are shown in Figs. 11a and 11b of the Burmeister WO publication.

The stent of claim 21, wherein the stent is made from Nitinol. Claim 31:

> The features of claim 21 are discussed above. The additional feature of claim 31 is recited in the Count.

Claim 32: The stent of claim 21, wherein each annular element comprises a plurality of alternating struts and apices connected to each other to form a substantially annular configuration, with at least one of the annular elements provided in an open configuration such that the plurality of alternating struts and apices are not connected at at least one location.

The features of claim 21 are discussed above. The additional features of claim 32 are disclosed in the Burmeister WO publication, the Goicoechea '627 patent, and the Fischell '825 patent, as discussed above in connection with claim 8.

Claim 33: A stent having a plurality of segments and comprising:

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a plurality of annular elements, each annular element having a compressed state and an expanded state;

a plurality of connecting members connecting adjacent annular elements; and a plurality of gaps formed by omitting at least one of the connecting members between adjacent annular elements so as to provide two of the plurality of segments of the stent with different degrees of flexibility.

The features of claim 33 are disclosed in the Count taken with Burmeister WO publication. The Count recites a stent having a plurality of annular elements and a plurality of connecting members. Burmeister further discloses that *omitting portions* in a stent can increase flexibility, page 12, lines 13-16, and illustrates omitting connectors in Figs. 9a-9b and 10a-10d. Burmeister expressly teaches that this may be done to other structures to improve flexibility. Page 12, lines 13-16. The stent of Figs. 10c and 10d, and the stent of Figs. 11a and 11b, both have segments with different degrees of flexibility.

Claim 34: The stent of claim 33, wherein a plurality of connecting members are omitted, with the omitted connecting members forming a spiral pattern.

The features of claim 33 are discussed above. The additional features of claim 34 are disclosed in the Burmeister WO publication and the Goicoechea '627 patent. Burmeister teaches omitting elements for the purpose of increasing flexibility, page 12, lines 13-16, and illustrates omitted elements in a spiral pattern in Figs. 8a and 8b. Goicoechea also shows a spiral pattern of omitted connecting members in Fig. 2A.

Claim 35: A stent having a plurality of segments and comprising:

a plurality of annular elements, each annular element having a compressed state and an expanded state;

a plurality of connecting members connecting adjacent annular elements; and wherein each annular element comprises a plurality of alternating struts and apices connected to each other to form a substantially annular configuration, and wherein the connecting members are connected to the apices of the adjacent annular elements;

and wherein a plurality of gaps are formed by omitting at least one of the struts so as to provide two of the plurality of segments of the stent with different degrees of flexibility.

The features of claim 35 are disclosed in the Count taken with the Burmeister WO publication. The Count recites a stent having a plurality of annular elements and a plurality of connecting members. Burmeister further discloses that omitting elements, such as connectors, in a stent can increase flexibility, as illustrated in Figs. 9a-9b, 10a-10d, and 11a-11b, and expressly teaches that this may be done to other structures to improve flexibility. Page 12, lines 13-16. The stents of Figs. 10c and 10d, and Figs. 11a and 11b, include a plurality of alternating struts and apices connected to each other to form a substantially annular configuration and have segments with different degrees of flexibility.

Claim 36: The stent of claim 35, wherein the plurality of gaps is further formed by omitting at least one of the connecting members between adjacent annular elements.

The features of claim 35 are discussed above. The additional features of claim 36 are disclosed in the Burmeister WO publication. The stents of Figs. 10c and 10d of Burmeister have gaps formed by omitting connecting members between adjacent annular elements of the stents of Figs. 10a and 10b. Stents with omitted connecting members are also shown in Figs. 11a and 11b.

Claim 37: The stent of claim 35, wherein a plurality of struts are omitted, with the omitted struts forming a spiral pattern.

The features of claim 35 are discussed above. The additional features of claim 37 are disclosed in the Burmeister WO publication and also in the Goicoechea '627 patent. Burmeister teaches omitting portions of the stent for the purpose of increasing flexibility, page 12, lines 13-16, and shows omission of

connectors in a spiral pattern in Figs. 8a and 8b. Goicoechea shows a spiral pattern of omitted struts in Fig. 2A.

Claim 38: A stent comprising:

a plurality of annular elements, each annular element having a compressed state and an expanded state, and each annular element including a plurality of alternating struts and apices connected to each other to form a substantially annular configuration; and at least one connecting member connecting adjacent annular elements; wherein at least one of the annular elements is closed such that the plurality of alternating struts and apices are connected to each other to form a closed annular element, and wherein at least one of the annular elements are open such that the plurality of alternating struts and apices are not connected at at least one location.

The features of claim 38 are disclosed in the Count taken with the Burmeister WO publication, further with the Goicoechea '627 patent, and the Fischell '825 patent, as discussed above in connection with claim 8.

Claim 39: The stent of claim 38, wherein the at least one connecting member is connected to the apices of the adjacent annular members.

The features of claim 38 are discussed above. Claim 39 recites features already at issue by way of claim 3 of the Roubin '321 patent, which has been copied as claim 24. The features of claim 39 are disclosed in the Burmeister WO publication at Figs. 11a and 11b.

Claim 40: The stent of claim 38, wherein the plurality of struts comprises left and right struts, with each pair of left and right struts connected to each other at an apex.

The features of claim 38 are discussed above. Claim 40 recites features already at issue by way of claim 4 of the Roubin '321 patent, which has been copied as claim 25. The features of claim 40 are disclosed in the Burmeister WO publication at Figs. 11a and 11b.

Claim 41: The stent of claim 38, wherein each strut has a longitudinal dimensional which is smaller when the annular elements are in the expanded state than in the compressed state.

The features of claim 38 are discussed above. Claim 41 recites features already at issue by way of claim 5 of the Roubin '321 patent, which has been copied as claim 26. The features of claim 41 are disclosed in the Burmeister WO publication at Figs. 11a and 11b.

Claim 42: The stent of claim 38, wherein each strut has a longitudinal dimensional which is larger when the annular elements are in the compressed state than in the expanded state.

The features of claim 38 are discussed above. Claim 42 recites features already at issue by way of claim 6 of the Roubin '321 patent, which has been copied as claim 27. The features of claim 42 are disclosed in the Burmeister WO publication at Figs. 11a and 11b.

Claim 43: The stent of claim 38, wherein the at least one connecting member has a plurality of alternating segments.

The features of claim 38 are discussed above. Claim 43 recites features already at issue by way of claim 9 of the Roubin '321 patent, which has been copied as claim 29. The features of claim 43 are disclosed in the Burmeister WO publication at Figs. 11a and 11b.

Claim 44: The stent of claim 43, wherein the at least one connecting member has a plurality of alternating curved segments defining alternating top and bottom curved apices.

The features of claim 43 are discussed above. The additional features of claim 44 are disclosed in the Fischell '312 patent, as discussed above in connection with claim 10.

Claim 45: The stent of claim 44, wherein the plurality of alternating curved segments have a higher amplitude and a smaller wavelength when the annular elements are in the expanded state than when the annular elements are in the compressed state.

The features of claim 44 are discussed above. The Burmeister WO publication and the Fischell '312 patent, as discussed above in connection with claim 11, disclose connectors that have curved segments that have an amplitude that decreases and a wavelength that increases when the stent is in the expanded state as compared to their dimensions in the compressed state. The additional features of claim 45 may be achieved by configuring the preset elasticity of the Count to achieve a higher amplitude and a smaller wavelength in the expanded state.

Moreover, claim 45 is invalid under 35 U.S.C. § 112, first paragraph. The specification of the Roubin '321 patent does not support alternating curved segments having a higher amplitude and a smaller wavelength when the annular

elements are in the expanded state as compared to the amplitude and wavelength of the stent in the compressed state. The Roubin '321 patent only supports a smaller amplitude and a larger wavelength in the expanded state.

Claim 46: The stent of claim 43, wherein the at least one connecting member has a plurality of alternating curved and straight segments.

The features of claim 43 are discussed above. The additional features of claim 46 are disclosed in the Fischell '312 patent, as discussed above in connection with claim 12.

Claim 47: The stent of claim 43, wherein the at least one connecting member has a plurality of alternating and angled straight segments.

The features of claim 43 are discussed above. Claim 47 recites features already at issue by way of claim 13 of the Roubin '321 patent, which has been copied as claim 30. The features of claim 47 are disclosed in the Burmeister WO publication at Figs. 11a and 11b.

Claim 48: The stent of claim 38, wherein the at least one connecting member is preset with an elasticity which causes the connecting member to elongate longitudinally when the annular elements are in their expanded state to compensate for the smaller longitudinal dimension of the annular elements in the expanded state.

The features of claim 38 are discussed above. The additional features of claim 48 are recited in the Count.

Claim 49: The stent of claim 48, wherein the stent is made from Nitinol.

The features of claim 48 are discussed above. The additional feature of claim 49 is recited in the Count.

Claim 50: The stent of claim 38, wherein the annular elements and the at least one connecting member define an alternating longitudinal pattern of annular elements and connecting members.

The features of claim 38 are discussed above. The additional features of claim 50 are shown in the Burmeister WO publication Figs. 10a-10b and 11a-11b.

Claim 51: The stent of claim 38, wherein the stent has a plurality of segments along its length, each segment assuming a different diameter when the annular elements are in their expanded state.

The features of claim 38 are discussed above. The additional features of claim 51 are disclosed in the Jang '484 application, the Fischell '825 patent, the Goicoechea '627 patent and the Burmeister WO publication, as discussed above in connection with claim 16.

Claim 52: The stent of claim 51, wherein the stent has a tapered configuration in which the diameter of the stent gradually changes from one segment to another segment.

The features of claim 51 are discussed above. The additional features of claim 52 are disclosed in the Jang '484 application, as discussed above in connection with claim 17.

Claim 53: The stent of claim 51, wherein the stent has a stepped configuration in which the diameter of the stent transitions abruptly from one segment to another segment.

The features of claim 51 are discussed above. The additional features of claim 53 are disclosed in the Goicoechea '627 patent, as discussed above in connection with claim 18.

Claim 54: The stent of claim 38, further in combination with a biocompatible graft covering.

The features of claim 38 are discussed above. The additional features of claim 54 are disclosed in the Goicoechea '627 patent and the Burmeister WO publication, as discussed above in connection with claim 19.

#### Roubin et al. U.S. 6,106,548

Claim 1: A stent having a plurality of segments and comprising:

a plurality of annular elements, each annular element having a compressed state and an expanded state;

at least one connecting member connecting adjacent annular elements to form a plurality of cells, each cell having an area;

the stent having a first segment and a second segment, with the first segment having a plurality of combined adjacent cells that impart greater flexibility to the first segment than the second segment;

wherein the annular elements and connecting members are made of Nitinol, with each connecting member preset with an elasticity which causes the connecting member to elongate longitudinally.

The features of claim 1 are disclosed in Count taken with the Burmeister WO publication, Figs. 11a and 11b. The Count recites a stent having a plurality

of annular elements, each annular element having a compressed and expanded state, and connecting members connecting adjacent annular elements. A stent as in Figs. 11a and 11b of the Burmeister WO publication has apertures defined by adjacent annular elements and connecting members.

The stent of Fig. 11a also has first segments and second segments, as indicated in the annotated version of Fig. 11a provided in Appendix A attached hereto. The cells of the first segments impart greater flexibility to the first segment at least because the connectors are not connected at each peak of the adjacent annular elements and because its connectors open or close further when subjected to bending force. Furthermore, Burmeister teaches that portions may be omitted to increase flexibility and illustrates such in Figs 10a-10d. Page 12, lines 13-16.

Claim 2: The stent of claim 1, wherein each annular element comprises a plurality of alternating struts and apices connected to each other to form a substantially annular configuration, and wherein the connecting members are connected to the apices of the adjacent annular members.

> The features of claim 1 are discussed above. The additional features of claim 2 are disclosed in the Burmeister WO publication, Figs. 11a and 11b. The additional features recited in this claim are already at issue by way of claims 2 and 3 of the Roubin '321 patent, which have been copied as claims 23 and 24, respectively.

Claim 3: The stent of claim 1, wherein the stent has a diameter, and has a tapered configuration in which the diameter of the stent gradually changes from one segment to another segment.

> The features of claim 1 are discussed above. The additional features of claim 3 are disclosed in the Jang '484 application. Jang identifies the desirability for a tapered stent at page 3, line 36 - page 4, line 5, and an embodiment of such a stent is disclosed at Fig. 8, page 16, lines 33-34, and page 24, line 10 - page 27, line 31. In Jang's Fig. 8, the segments G, H, I, J have different lengths relative to each other and to the lengths of segments A-F. This difference produces different diameters for each segment F-J when the stent is expanded. The stent can be

made of Nitinol, page 12, line 16, and may be self-expanding. Page 12, line 20. Differential segment lengths along a stent of the Count accommodates body vessel taper.

Claim 4:

The stent of claim 1, wherein the stent has a diameter, and has a stepped configuration in which the diameter of the stent transitions abruptly from one segment to another segment.

The features of claim 1 are discussed above. The additional features of claim 4 are disclosed in the Goicoechea '627 patent. In Goicoechea's Fig. 1A, the transition region 14 is short relative to segments 12 and 16 and is therefore "abrupt."

Claim 5:

The stent of claim 1, wherein the difference in flexibility between the first and second segments is a difference in the longitudinal flexibilities in the first and second segments.

The features of claim 1 are described above. The additional features of claim 5 are disclosed in the Burmeister WO publication. The stents of Burmeister shown in Fig. 11a and 11 b have a first segment and a second segment with a difference in longitudinal flexibility. The longitudinal flexibility can be increased by omitting connectors as taught on page 12 lines 13-16.

Claim 6:

The stent of claim 1, wherein the difference in flexibility between the first and second segments is a difference in the radial flexibilities in the first and second segments.

The features of claim 1 are described above. The additional features of claim 6 are disclosed in the Burmeister WO publication and the Goicoechea '627 patent. The stents of Burmeister have a first segment and a second segment with a difference in radial flexibility that allows the stent to articulate. The stent's flexibility for articulation is increased by omitting connectors as taught on page 12 lines 13-16. In addition, a stent made in the manner of Fig. 1A of Goicoechea, will have different radial flexibilities between the stent segments corresponding to parts 12, 14, and 16 of Fig. 1A of Goicoechea.

Claim 7: The stent of claim 1, wherein the first and second segments are spaced apart longitudinally along the stent.

The features of claim 1 are described above. The additional features of claim 7 are disclosed in the Burmeister WO publication. As shown in Figs. 11a and 11b, the first and second segments alternate along the stent and as such are seen to be spaced apart longitudinally.

Claim 8:

A stent having a first end, an opposing second end, and a longitudinal length, the stent having a diameter throughout its length and comprising:

a plurality of annular elements, each annular element having a compressed state and an expanded state; and

the stent having a tapered configuration in the expanded state with the diameter of the stent continuously increasing from a first diameter at the first end to a second greater diameter at the second end:

wherein the first and second ends have different degrees of flexibility.

The features of claim 8 are disclosed in the Count taken with the Jang '484 application. The annular elements, and the compressed and expanded states are recited in the Count. The two ends and longitudinal length are inherent. Jang teaches a stent having a tapered configuration in the expanded state. As depicted in Fig. 8, Jang teaches a stent having a tapered portion and further discloses that the taper may extend over a wider range than specifically illustrated in Fig. 8. Page 25, lines 21-25. Jang also identifies the desirability for a tapered stent at page 3, line 36 - page 4, line 5. A tapered stent made in the manner of Jang will have different flexibility at its two ends; where longitudinal flexibility will diminish as the struts shorten. Differential segment lengths along a stent accommodates body vessel taper.

Claim 9:

The stent of claim 8, wherein the stent is expanded to its expanded state and then preset at this expanded state to have a continuously changing diameter.

The features of claim 8 are described above. The additional features of claim 9 are disclosed in the Goicoechea '627 patent and the Jang '484 application. Jang teaches that the stent may be self expanding and made of Nitinol, page 12, lines 6-20, and the Count also recites Nitinol. Goicoechea teaches that a selfexpanding Nitinol stent may be made by providing the stent in the expanded state and annealing at that state so the metal "remembers" that configuration. Col. 9,

line 31-38. A tapered stent of the Count taken with Jang and made of Nitinol would be preset at the expanded state to have a continuously changing diameter when annealed in the manner of Goicoechea.

Claim 10: The stent of claim 8, wherein the stent is self-expanding.

The features of claim 8 are described above. The additional feature of claim 10 is seen to be met by the Nitinol and preset elasticity recitations of the Count. The Burmeister WO publication also teaches that the devices of that invention are preferably made of shape memory alloys, such as Nitinol, that includes at least one component which exhibits a tendency to self expand the device. Page 2, lines 2-27. The Jang '484 application teaches that his stents may be made of Nitinol and self-expanding as well. Page 12, lines 18-20.

Claim 11: The stent of claim 10, wherein the stent is made of a shape-memory material.

The features of claim 10 are described above. The additional feature of claim 11 is seen to be met by the Nitinol and preset elasticity recitations of the Count, as discussed in connection with claim 10. The Burmeister WO publication and the Jang '484 application also disclose the added feature as discussed in connection with claim 10.

Claim 12: The stent of claim 8, wherein each annular element comprises a plurality of alternating struts and apices connected to each other to form a substantially annular configuration, and wherein the stent further includes connecting members that are connected to the apices of the adjacent annular members, with all the struts in the stent having the same length in the expanded state.

The features of claim 8 are described above. The additional features of claim 12 are disclosed in the Burmeister WO publication. As the Burmeister stent expands, all of the struts will have the same expanded length since the unexpanded struts are all constructed from the same material having the same length, width and thickness. It is also noted that the added limitation in this claim is already at issue by way of claim 2 of the Roubin '321 patent, which has been copied as claim 23.

#### Roubin et al. U.S. 6,475,236

Claim 1:

A stent having a longitudinal length, a compressed state and an expanded state, the stent comprising:

a plurality of annular elements;

the stent having a first segment and a second segment;

wherein the first and second segments have different diameters when the stent is in the expanded state; and

wherein the length of the stent remains the same in both the compressed and expanded states.

The features of claim 1 are disclosed in the Count taken with the Jang '484 application. The Count recites annular elements, and the compressed and expanded states. Jang discloses first and second segments having different diameters in the expanded states to accommodate body vessel taper. Page 16, lines 33-34; page 24, line 10 - page 27, line 31; and Fig. 8. Jang further teaches the desirability of minimizing foreshortening, page 10, lines 3-21, which would be minimized with stents configured to have the same length in both the compressed and the uncompressed states.

Claim 2: The stent of claim 1, wherein each annular element comprises a plurality of alternating struts and apices connected to each other to form a substantially annular configuration.

The features of claim 1 are discussed above. Claim 2 recites features already at issue by way of claim 2 of the Roubin '321 patent, which has been copied as claim 23. The features of claim 2 are disclosed in the Burmeister WO publication at Figs. 11a and 11b.

Claim 3: The stent of claim 2, further including connecting members connected to the apices of the adjacent annular members.

The features of claim 2 are discussed above. Claim 3 recites features already at issue by way of claim 3 of the Roubin '321 patent, which has been copied as claim 24. The features of claim 3 are disclosed in the Burmeister WO publication at Figs. 11a and 11b.

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The stent of claim 2, wherein each strut has a longitudinal dimensional which is smaller Claim 4: when the annular elements are in the expanded state than in the composed state.

> The features of claim 2 are discussed above. Claim 4 recites features already at issue by way of claim 5 of the Roubin '321 patent, which has been copied as claim 26. The features of claim 4 are disclosed in the Burmeister WO publication at Figs. 11a and 11b.

Claim 5: The stent of claim 2, wherein each strut has a longitudinal dimensional which is larger when the annular elements are in the compressed state than in the expanded state.

> The features of claim 2 are discussed above. Claim 5 recites features already at issue by way of claim 6 of the Roubin '321 patent, which has been copied as claim 27. The features of claim 5 are disclosed in the Burmeister WO publication at Figs. 11a and 11b.

Claim 6: The stent of claim 1, wherein the first and second segments have different degrees of flexibility.

> The features of claim 1 are discussed above. The additional features of claim 6 are disclosed in the Burmeister WO publication at Figs. 11a and 11b. The Jang '484 application Fig. 8 discloses segments with different flexibilities between the segments F-J as a result of the difference between the lengths of the struts.

Claim 7: The stent of claim 1, wherein the length of the stent is consistently maintained throughout the expansion of the stent from the compressed state to the expanded state.

> The features of claim 1 are discussed above. The additional features of claim 7 are disclosed in the Jang '484 application. Jang discloses stents with minimal changes in length upon expansion, page 6, line 2, which would inherently be consistently maintained throughout the expansion of the stent shown in Fig. 3.

Claim 8: A stent having a longitudinal length, a compressed state and an expanded state, the stent comprising:

a plurality of annular elements;

the stent having a first segment and a second segment;

wherein the first and second segments have different diameters when the stent is in the expanded state;

wherein the length of the stent remains the same in both the compressed and expanded states; and

wherein the stent is expanded to its expanded state and then preset at this expanded state in a manner such that the diameters of the first and second segments are different.

The features of claim 8 are disclosed in the Count taken with the Jang '484 application and the Goicoechea '627 patent. The Count recites annular elements, and the compressed and expanded states. Jang discloses first and second segments having different diameters in the expanded states to accommodate body vessel taper. Page 16, lines 33-34; page 24, line 10 - page 27, line 31; and Fig. 8. Jang further teaches the desirability of minimizing foreshortening, page 10, lines 3-21, which would be minimized with stents configured to have the same length in both the compressed and the uncompressed states. The Count recites Nitinol. Jang further discloses self-expanding stents made of Nitinol, page 12, lines 6-20. Goicoechea discloses self-expanding Nitinol stents annealed in an expanded state so the metal "remembers" that configuration. Col. 9, line 31-38. A tapered stent of the Count taken with Jang and made of Nitinol would be preset at the expanded state such that the diameters of the first and second segments are different when annealed in the manner of Goicoechea.

Claim 9: A stent having a compressed state and an expanded state, the stent comprising:

a plurality of annular elements that define a plurality of apertures;

the stent having a first segment and a second segment;

wherein the first and second segments have different diameters when the stent is in the expanded state; and

wherein all the apertures in the stent have a uniform size when in the compressed state.

The features of claim 9 are recited in the Count taken with the Burmeister WO publication and the Jang '484 application. The stent of the Count illustrated in Burmeister Figs. 11a and 11b has a compressed state, an expanded state, and a

plurality of annular elements that define adjacent annular elements. In the compressed state shown in Fig. 11a, aperture width in the circumferential direction is uniform. Jang discloses a tapered stent having multiple segments that have different diameters in the expanded state but the same diameter in the compressed state. Page 16, lines 33-34; page 24, line 10 - page 27, line 31; and Fig. 8. Fig. 3 further shows apertures having a uniform width along the longitudinal axis of the stent in the compressed state.

Claim 10: The stent of claim 9, wherein each annular element comprises a plurality of alternating struts and apices connected to each other to form a substantially annular configuration.

The features of claim 9 are discussed above. Claim 10 recites features already at issue by way of claim 2 of the Roubin '321 patent, which has been copied as claim 23. The features of claim 10 are disclosed in the Burmeister WO publication at Figs. 11a and 11b.

Claim 11: The stent of claim 10, wherein each strut has a longitudinal dimensional which is smaller when the annular elements are in the expanded state than in the compressed state

The features of claim 10 are discussed above. Claim 11 recites features already at issue by way of claim 5 of the Roubin '321 patent, which has been copied as claim 26. The features of claim 11 are disclosed in the Burmeister WO publication at Figs. 11a and 11b.

Claim 12: The stent of claim 9, wherein the stent has a longitudinal length which remains the same in both the compressed and expanded states.

The features of claim 9 are discussed above. The additional features of claim 12 are disclosed in the Jang '484 application, as discussed above in connection with claim 8.

Claim 13: A stent having a compressed state and an expanded state, the stent comprising: a plurality of annular elements;

a plurality of curved longitudinal elements that have a greater amplitude and shorter wavelength when the stent is in the compressed state than when the stent is in the expanded state;

the stent having a first segment and a second segment; and

wherein the first and second segments have different diameters when the stent is in the expanded state.

The features of claim 13 are disclosed in the Count taken with the Burmeister WO publication, the Fischell '312 patent, and the Jang '484 application. A stent of the Count as illustrated in Figs. 11a and 11b of Burmeister has compressed and expanded states, annular elements, longitudinal connectors that have a greater amplitude and a shorter wavelength when in the compressed state in comparison to that of the expanded state and first and second segments, as discussed above in connection with claim 1 of the Roubin '548 patent. Fischell Fig. 8, shows the use of curved longitudinal connections (14L and 14R) for flexibility. As discussed in connection with claim 8, Jang teaches a stent having a tapered portion. The tapered portion has first and second segments that have different diameters when the stent is in the expanded state.

Claim 14: The stent of claim 13, wherein each annular element comprises a plurality of alternating struts and apices connected to each other to form a substantially annular configuration.

The features of claim 13 are described above. Claim 14 recites features already at issue by way of claim 2 of the Roubin '321 patent, which has been copied as claim 23. The additional features of claim 14 are disclosed in the Burmeister WO publication in Figs. 11a and 11b.

Claim 15: The stent of claim 14, wherein each strut has a longitudinal dimensional which is smaller when the annular elements are in the expanded state than in the compressed state.

The features of claim 14 are described above. Claim 15 recites features already at issue by way of claim 5 of the Roubin '321 patent, which has been copied as claim 26. The additional features of claim 15 are disclosed in the Burmeister WO publication Figs. 11a and 11b, Fig. 8 of the Fischell '312 patent, and Fig. 8 of the Jang '484 application.

Claim 16: The stent of claim 14, wherein each strut has a longitudinal dimensional which is larger when the annular elements are in the compressed state than in the expanded state.

The features of claim 14 are described above. Claim 16 recites features already at issue by way of claim 6 of the Roubin '321 patent, which has been copied as claim 27. The additional features of claim 16 are disclosed in the Burmeister WO publication Figs. 11a and 11b, Fig. 8 of the Fischell '312 patent, and Fig. 8 of the Jang '484 application.

Claim 17: The stent of claim 13, wherein the stent has a longitudinal length that remains the same in both the compressed and expanded states.

The features of claim 13 are described above. The additional feature of claim 17 is disclosed in the Burmeister WO publication and the Jang '484 application. The stent of the Count has a length compensating feature and Jang teaches producing a stent with no change in length, as discussed above in connection with claim 1.

Claim 18: The stent of claim 13, further including a plurality of apertures defined by adjacent annular elements, wherein each of the plurality of apertures has a geometric shape, with the geometric shape of all the apertures being the same when the stent is in the expanded state.

The features of claim 13 are described above. The additional features of claim 18 are disclosed in the Goicoechea '627 patent as discussed in connection with claim 21 of the Roubin '321 patent.

Claim 19: A stent having a longitudinal length, a compressed state and an expanded state, the stent comprising:

a plurality of annular elements, each annular element having a plurality of straight struts and a plurality of apices;

a plurality of longitudinal connecting members connected to the apices of adjacent annular elements;

the stent having a first segment and a second segment;

wherein the first and second segments have different diameters when the stent is in the expanded state;

wherein all the straight struts in the stent have the same length through the stent; and

wherein all the connecting members in the stent have the same length through the stent

The features of claim 19 are disclosed in the Count taken with the Burmeister WO publication, and the Fischell '825 patent. The Count recites a

stent having a plurality of annular elements and a plurality of longitudinal connecting members. In Figs. 11a and 11b of Burmeister, the annular elements each have a plurality of straight struts that are all the same length and a plurality of apices, with connectors that are all of the same length, connected to the apices of longitudinally adjacent annular elements. The struts and connectors are the same length throughout the stent.

Fischell shows a stent that has struts and connectors having the same length and that has first and second segments having different diameters when the stent is in the expanded state (Fig. 5).

Claim 20: The stent of claim 19, wherein the length of the stent remains the same in both the compressed and expanded states.

The features of claim 19 are described above. The additional feature of claim 20 is disclosed in the Jang '484 application. Jang teaches the desirability of minimizing foreshortening as discussed above for claim 1. In addition, the stent of the Count has foreshortening compensation.

Claim 21: A stent having a compressed state and an expanded state, the stent comprising: a plurality of annular elements;

connecting members connected to adjacent annular elements, the connecting members being preset with an elasticity which causes each connecting member to elongate longitudinally when the stent is in the expanded state to compensate for the smaller longitudinal dimension of the annular elements in the expanded state;

the stent having a first segment and a second segment; and wherein the first and second segments have different diameters when the stent is in the expanded state.

The features of claim 21 are disclosed in the Count taken with the Jang '484 application. A stent as recited in the Count has a compressed state, an expanded state, a plurality of annular elements, and connecting members having a preset elasticity as recited in claim 21. As discussed above in connection with claim 8, Jang teaches a tapered stent. The stent of Jang's Fig. 8 has first and second segments having different diameters when the stent is in the expanded state.

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NOTE: There is no antecedent basis for the phrase "the smaller." The claim is invalid under 35 U.S.C. § 112, second paragraph.

Claim 22: The stent of claim 21, wherein the stent has a longitudinal length that remains the same in both the compressed and expanded states.

The features of claim 21 are described above. The additional feature of claim 22 is disclosed in the Jang '484 patent, as discussed in connection with claim 20.

Claim 23: A stent having a longitudinal length, a compressed state and an expanded state, the stent comprising:

a plurality of annular elements, with a plurality of apertures defined by adjacent annular elements;

the stent having a first segment and a second segment:

wherein the first and second segments have different diameters when the stent is in the expanded state; and

wherein each of the plurality of apertures has a geometric shape, with the geometric shape of all the apertures being the same when the stent is in the compressed state.

The features of claim 21 are disclosed in the Count taken with the Burmeister WO publication, and the Jang '484 application. The stent of the Count has a compressed state, an expanded state, a plurality of annular elements and a plurality of apertures defined by adjacent annular elements. As shown in Burmeister Figs. 10a and 10b, all of the apertures are the same shape in the compressed state. As discussed above in connection with claim 8, Jang teaches a tapered stent.

Claim 24: The stent of claim 23, wherein all the apertures in the stent have a uniform size when in the compressed state.

The features of claim 23 are described above. The additional features of claim 24 are disclosed in the Burmeister WO publication, Referring to Fig. 10a of Burmeister, a uniform aperture size is depicted for of the apertures in the compressed state.

Claim 25: The stent of claim 23, wherein the stent has a longitudinal length that remains the same in both the compressed and expanded states.

The features of claim 23 are described above. The additional feature of claim 25 is disclosed in the Jang '484 patent, as discussed for claim 20 above.

#### Roubin et al. U.S. Application No. 10/892,718, filed on July 16, 2004

One claim is pending as follows:

#### Claim 1:

A stent comprising:

a plurality of annular elements, each annular element having a compressed state and an expanded state, wherein each annular element has a longitudinal dimension which is smaller in the radially expanded state than in the compressed state; and

at least one connecting member connecting adjacent annular elements, the connecting member operating to compensate for the smaller longitudinal dimension of the annular elements in the expanded state.

The Count meets all of the recitations of the pending claim 1. The claim is not patentable to Roubin over the Count.

#### Burmeister et al: U.S. Application No. 09/427,291, Claims 22-32 and 34.

#### Claim 22:

A stent comprising:

a plurality of annular elements, each annular element having a compressed state and an expanded state, wherein each annular element has a longitudinal dimension which is smaller in the radially expanded state than in the compressed state; and

connecting members connecting adjacent annular elements;

wherein the annular elements and connecting members are made of Nitinol, with each connecting member preset with an elasticity which causes the connecting member to elongate longitudinally when the annular elements are in their expanded state to compensate for the smaller longitudinal dimension of the annular elements in the expanded state.

Claim 22 is not patentable over the Count. Claim 22 is The Count.

#### Claims 23-32 and 34:

The claims depend from a claim that is the Count and have been copied from claims 2-7, 9, 13-15, and 20 of Roubin '321.

#### VIII. Claim Chart showing interfering subject matter 37 C.F.R. § 41.202(a)(3)

Roubin U.S. 5,827,321	Burmeister U.S. Application 09/427,291	Interfering Subject Matter
1. A stent comprising:	22. A stent comprising:     a plurality of annular elements,     each annular element having a     compressed state and an expanded     state, wherein each annular element has     a longitudinal dimension which is smaller     in the radially expanded state than in the     compressed state; and         connecting members     connecting adjacent annular elements;         wherein the annular elements     and connecting members are made of     Nitinol, with each connecting member     preset with an elasticity which causes the     connecting member to elongate     longitudinally when the annular elements     are in their expanded state to     compensate for the smaller longitudinal     dimension of the annular elements in the     expanded state.	The claims are identical to each other and to the Count. The two-way unpatentability test under 37 C.F.R. § 41.203(a) is satisfied on the basis that both the Roubin '321 patent and the Burmeister '291 application have a claim identical to the proposed count.

Although 37 C.F.R. § 41.203 is understood to only require a showing of two-way unpatentability between one claim of each party for each count, it bears repeating that Roubin '321 claims 2-7, 9, 13-15, and 20 and Applicants' claims 23-32 and 34, are identical. Therefore, each matching pair of dependent claims also meets the two-way unpatentablity test of § 41.203(a).

# IX. Detailed Explanation Why Applicants Will Prevail On Priority (37 C.F.R. § 41.202(a)(4))

Applicants are entitled to a constructive reduction to practice at least of as early as May 18, 1995, which is the filing date of the PCT application. This is more than one year before Roubin et al.'s earliest filing date of February 7, 1997 and entitles Applicants to senior party status.

Applicants are further entitled to a constructive filing date as of the filing date of the Burmeister '320 application that was filed May 19, 1994, which is more than 2 years before Roubin et al.'s earliest filing date.

Applicants are further entitled to an invention date earlier than May 19, 1994, based upon at least a conception prior to that date.

### X. Written Description Claim Chart (37 C.F.R. § 41.202(a)(5))

Support in the application for claims 22-32 and 34, the claims copied from the Roubin

Copied Claim	09/427,291
22. A stent comprising:  a plurality of annular elements, each annular element having a compressed state and an expanded state, wherein each annular element has a longitudinal dimension which is smaller in the radially expanded state than in the compressed state; and connecting members connecting adjacent annular elements;	In Figures 11a and 11b, a stent having annular elements and connecting members is shown. In the modified reproduction of those figures shown below, the compressed state is shown in Fig. 11a and the expanded state in Fig. 11b. The annular elements are unshaded whereas one of the connecting elements is shaded:  **Fig. 11a**  Because the angle <b 11a="" 11b,="" annular="" compressed="" decreases="" dimension="" element="" elements="" expanded="" fig.="" from="" in="" is="" longitudinal="" of="" radially="" smaller="" state="" state.<="" td="" than="" the="" to=""></b>
wherein the annular elements and connecting members are made of Nitinol,	Preferred embodiments make use of shape memory alloys, {page 2, lines 12-13, page 5, lines 1-4}. The application focuses on well-known Ni-Ti alloys, which have particularly pronounced shape memory and superelasticity properties {page 2, lines 20-21, page 5, lines 17-20}. Such Ni-Ti alloys are also referred to as "Nitinol" {page 10, lines 17-20}.
with each connecting member preset with an elasticity which causes the connecting member to elongate longitudinally when the annular elements are in their expanded state to compensate for the smaller	Self-expansion is caused by a shape memory characteristic built into the stent by various fabrication and manipulation techniques. Shape memory is an elasticity property {page 5, lines 5-7}.

longitudinal dimension of the annular elements in the expanded state.	With respect to Figure 11a, the stent is preset to self-expand to the configuration of Figure 11b. Thus the application teaches that the material of the stents of the invention have a <i>preset elasticity</i> which causes the stent to assume the configuration to which it self-expands. Since Figure 11b depicts the condition to which the stent of Figure 11a self-expands, the stent of Figure 11a has a preset elasticity to assume the condition of Figure 11b.  The preset elasticity of the stent of Figure 11a causes the longitudinal length of the radial bands to decrease and the longitudinal length of the connector to increase. This "necessarily" results from the basic geometry changes which occur as the stent transitions from Figures 11a to 11b, as can be seen from the modified reproduction above where one of the relevant connectors has been highlighted with shading and two angles are labeled.
23. The stent of claim 22, wherein each annular element comprises a plurality of alternating struts and apices connected to each other to form a substantially annular configuration.	The relevant parts of the Fig. 11a and 11b have been numbered on the page of drawings below. For this claim, alternating struts are shown at 114, apices at 116.:
	Fig. 11b  Fig. 11b  Fig. 11b  Fig. 11b  Fig. 11b  Fig. 11b
24. The stent of claim 23, wherein the connecting members are connected to the apices of the adjacent annular members.	In Figs. 11a and 11b the connecting members are connected to the apices of the adjacent annular members.
25. The stent of claim 23, wherein the plurality of struts comprises left and right struts, with each pair of left and right struts connected to each other at an apex.	In the modified Figs. 11a and 11b used with claim 23, left struts are indicated at 114a, right struts at 114b.
26. The stent of claim 23, wherein each strut has a longitudinal dimensional which is smaller when the annular elements are in the expanded state than in the compressed state.	In the modified Figs. 11a and 11b struts 114a and 114b orient at an oblique angle relative to longitudinal axis of the stent in the expanded state as shown an Fig. 11b, thereby producing a reduced longitudinal dimension on expansion from Fig. 11a where the struts 114 are parallel to the longitudinal axis of the stent.

27. The stent of claim 23, wherein each strut has a longitudinal dimensional which is larger when the annular elements are in the compressed state than in the expanded state.	There is no difference in scope between claim 26 and claim 27. The support is the same as the previous claim.
28. The stent of claim 23, wherein at least one of the annular elements is closed such that the plurality of alternating struts and apices are connected to each other to form a closed annular element.	All of the annular elements are closed. See copy of Figs. 11a and 11b used with claim 22.
29. The stent of claim 22, wherein at least of connecting member has a plurality of alternating segments.	In the modified Figs. 11a and 11b used with claim 23, segments 112a - 112c.
30. The stent of claim 29, wherein the at least one connecting member has a plurality of alternating and angled straight segments.	In the modified Figs. 11a and 11b used with claim 23, segments 112a and 112c are angled relative to the longitudinal axis of the stent.
31. The stent of claim 22, wherein each connecting member has a larger longitudinal dimension when each annular element is in the expanded state than in the compressed state to compensate for the smaller longitudinal dimension of the annular element in the expanded state.	This feature of the compressed and expanded states has already been discussed and shown in connection with claim 22, above.
32. The stent of claim 22, wherein each connecting member has a smaller longitudinal dimension when each annular element is in the compressed state than in the expanded state to compensate for the larger longitudinal dimension of the annular element in the compressed state.	This feature is an alternate phrasing for the same feature recited in claim 31. It has already been discussed and shown in connection with claim 22, above.
34. The stent of claim 1, wherein the annular elements and connecting members define an alternating longitudinal pattern of annular elements and connecting members.	In Figs. 11a and 11b the annular elements alternate along the longitudinal axis of the stent.

## XI. Constructive Reduction to Practice Chart (37 C.F.R. § 41.202(a)(6))

Count	PCT/US95/06228 published as WO 95/31945	U.S. Application No. 08/246,320
A stent comprising:  a plurality of annular elements, each annular element having a compressed state and an expanded state, wherein each annular element has a longitudinal dimension which is smaller in the radially expanded state than in the compressed state; and connecting members connecting adjacent annular elements;	In Figures 11a and 11b, a stent having annular elements and connecting members is shown. In the modified reproduction of those figures shown below, the compressed state is shown in Fig.11a and the expanded state in Fig. 11b. The annular elements are unshaded whereas the connecting elements are shaded:  *Fig. 11a*  Because the angle <b 11a="" 11b,="" annular="" compressed<="" decreases="" dimension="" element="" elements="" expanded="" fig.="" from="" in="" is="" longitudinal="" of="" radially="" smaller="" state="" td="" than="" the="" to=""><td>The disclosure of the stent of Figs.11a and 11b is the same. Fig. 11a is not found in the USPTO file of the application. However it is in the formal drawings filed August 25, 1994, and was actually filed with the application as verified in the accompanying petition to correct ancestor application. Support is therefore the same for these elements as for PCT/US95/06228 published as WO 95/31945.</td></b>	The disclosure of the stent of Figs.11a and 11b is the same. Fig. 11a is not found in the USPTO file of the application. However it is in the formal drawings filed August 25, 1994, and was actually filed with the application as verified in the accompanying petition to correct ancestor application. Support is therefore the same for these elements as for PCT/US95/06228 published as WO 95/31945.
wherein the annular elements and connecting members are made of Nitinol,	state.  Preferred embodiments make use of shape memory alloys, {page 2, lines 12-13, page 5, lines 1-4}. The application focuses on well-known Ni-Ti alloys, which have particularly pronounced shape memory and superelasticity properties {page 2, lines 20-21, page 5, lines 15-17}. Such Ni-Ti alloys are also referred to as "Nitinol" {page 10, lines 14-18}.	Preferred embodiments make use of shape memory alloys, {page 2, lines 16-17, page 4, lines 9-11}. The application focuses on well-known Ni-Ti alloys, which have particularly pronounced shape memory and superelasticity properties {page 4, lines 25-25}.
with each connecting member preset with an elasticity which causes the connecting member to elongate longitudinally when the annular elements are in their expanded state to compensate for	Self-expansion is caused by a shape memory characteristic built into the stent by various fabrication and manipulation techniques. Shape memory is an elasticity property {page 5, lines 3-5}.  With respect to Figure 11a, the stent is	Self-expansion is caused by a shape memory characteristic built into the stent by various fabrication and manipulation techniques. Shape memory is an elasticity property {page 4, lines 14-16}.

the smaller longitudinal dimension
of the annular elements in the
expanded state.

preset to self-expand to the configuration of Figure 11b. Thus the application teaches that the material of the stents of the invention have a *preset elasticity* which causes the stent to assume the configuration to which it self-expands. Since Figure 11b depicts the condition to which the stent of Figure 11a self-expands, the stent of Figure 11a has a preset elasticity to assume the condition of Figure 11b.

The preset elasticity of the stent of Figure 11a causes the longitudinal length of the radial bands to decrease and the longitudinal length of the connector to increase. This "necessarily" results from the basic geometry changes which occur as the stent transitions from Figures 11a to 11b, as can be seen from the modified reproduction above where one of the relevant connectors has been highlighted with shading and two angles are labeled.

The preset elasticity and lengthening of the connector with expansion of the stent from the configuration of Fig. 11a to Fig. 11b follow the same reasoning as used for PCT/US95/06228 published as WO 95/31945.

#### XII. Conclusion

Applicants have updated their request for an interference filed in 1999 and have provided the information in a format complying with the intervening new rule for suggesting interference, 37 C.F.R. § 41.202. Applicants therefore request that the interference be declared with one Count as follows:

#### The Count:

A stent comprising:

a plurality of annular elements, each annular element having a compressed state and an expanded state, wherein each annular element has a longitudinal dimension which is smaller in the radially expanded state than in the compressed state; and

connecting members connecting adjacent annular elements;

wherein the annular elements and connecting members are made of Nitinol, with each connecting member preset with an elasticity which causes the connecting member to elongate longitudinally when the annular elements are in their expanded state to compensate for the smaller longitudinal dimension of the annular elements in the expanded state.

The claims designated as corresponding to the Count should be:

Roubin et al.:

U.S. 5,827,321, claims 1-54;

Application No.: 09/427,291 August 25, 2005

Letter Supplementing and Amending Request for Interference Page 38

U.S. 6,106,548, claims 1-12; U.S. 6,475,236, claims 1-25; and

U.S. Application No. 10/892,718, claim 1.

Burmeister et al.:

U.S. Application No. 09/427,291, claims 22-32 and 34.

Applicants should be designated the Senior party at least on the basis of entitlement to benefit of U.S. Application No. 08/737,492, which is effective as of its May 18, 1995 PCT filing date, and further on the basis of entitlement to benefit of the Burmeister '320 application, filed May 19, 1994. Roubin et al. should be designated the junior party on the basis of U.S. Application No. 08/797,814, filed February 7, 1997.

Applicants further request that in the declaration of the interference, they be accorded a priority date, and therefore a prima facie constructive reduction to practice, at least as early as May 19, 1994 based upon the filing of the Burmeister '320 application and at least as early as May 18, 1995 based upon the filing of the Burmeister PCT application...

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS, P.A.

Date: 8/25/2005

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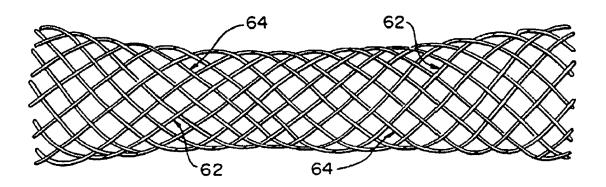
Attachment: Appendix A (12 pgs)



## APPENDIX A

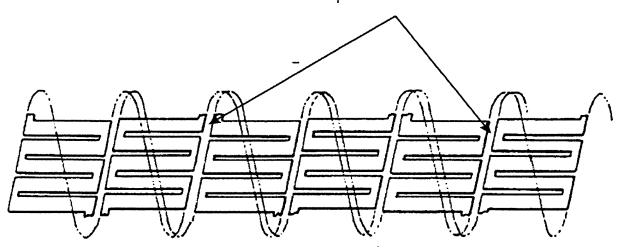
## THE BURMEISTER WO PUBLICATION

## FIGURE 6



#### FIGURE 8a - Annotated

Omission of Connectors in a Spiral Pattern



#### FIGURE 8b - Annotated

Omission of Cnnectors in a Spiral Pattern

## FIGURE 9a - Annotated

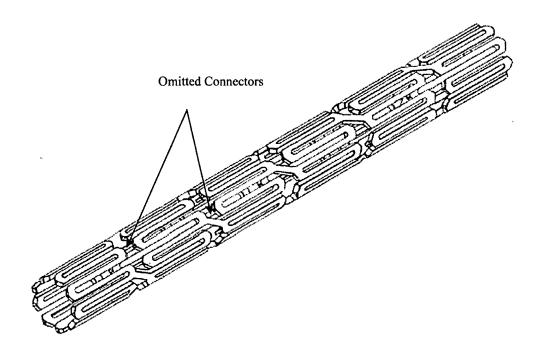
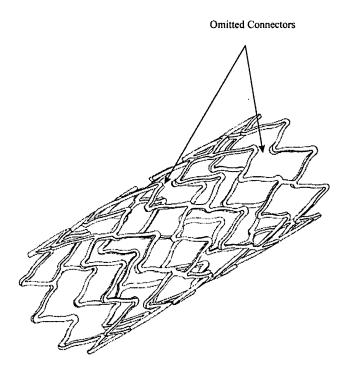
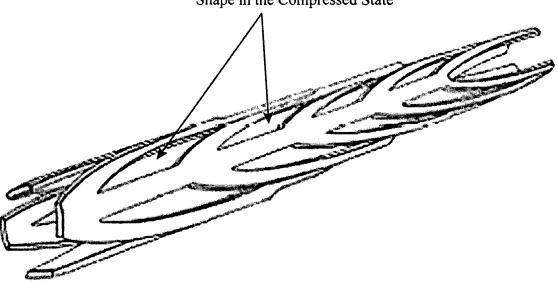


FIGURE 9b - Annotated

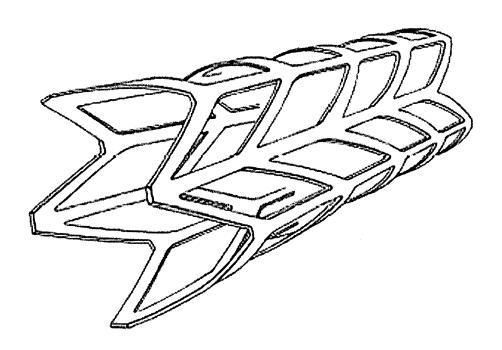


#### FIGURE 10a - Annotated

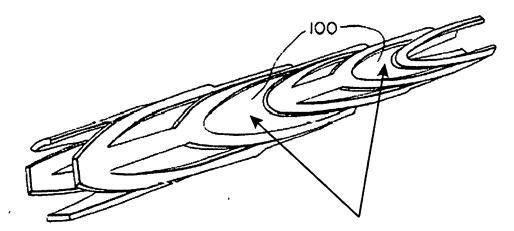
Apertures Having the Same Geometric Shape in the Compressed State



**FIGURE 10b** 

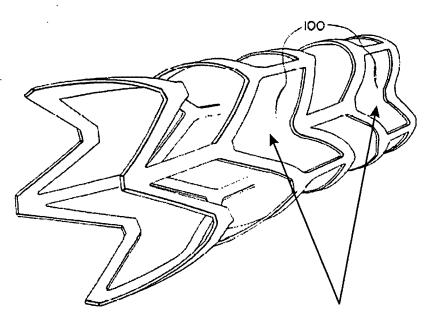


#### FIGURE 10c - Annotated



Gaps Formed by Omitting Connecting Members Between Adjacent Annular Elements

#### FIGURE 10d - Annotated



Gaps Formed by Omitting Connecting Members Between Adjacent Annular Elements

#### FIGURE 11a - Annotated

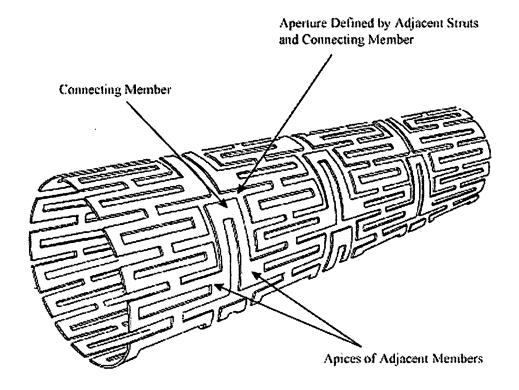
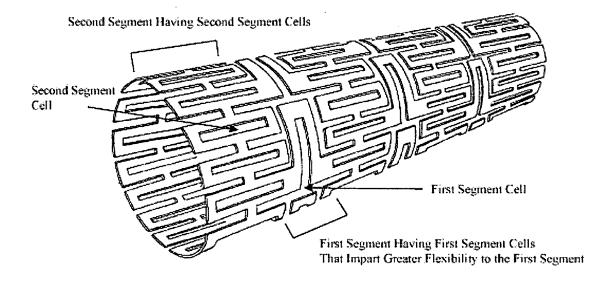
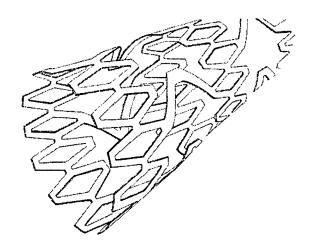


FIGURE 11a - Annotated

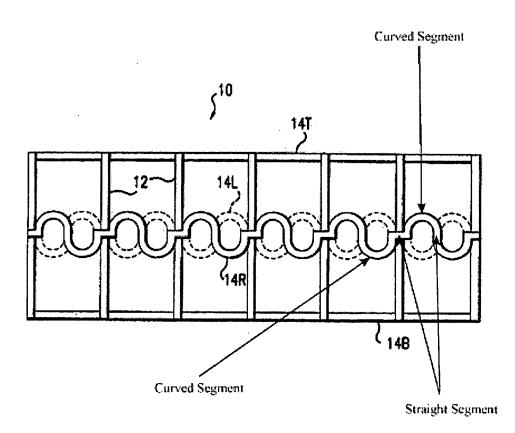


#### FIGURE 11b



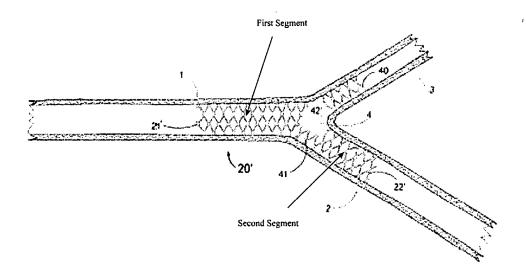
## **THE FISCHELL '312 PATENT**

## FIGURE 8 - Annotated



#### THE FISCHELL '825 PATENT

## FIGURE 5



## **THE '627 GOICOECHEA PATENT**

#### FIGURE 1A - Annotated

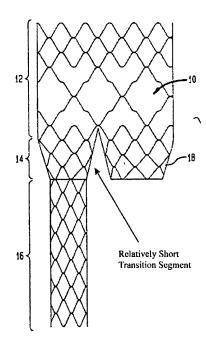


FIGURE 2A - Annotated

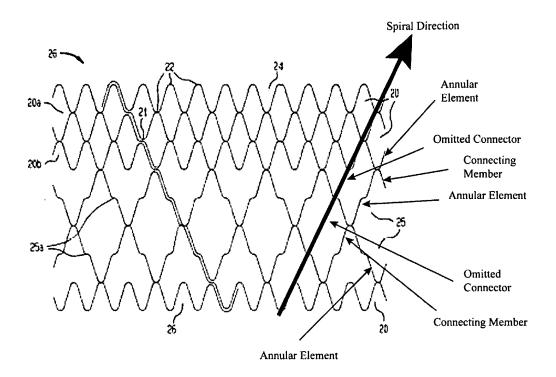


FIGURE 13 - Annotated

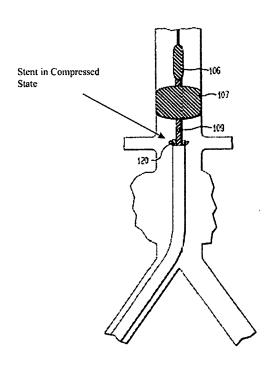


FIGURE 14 - Annotated

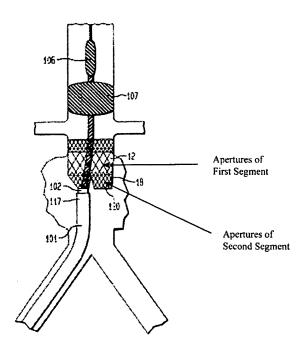
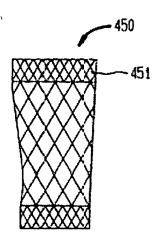


FIGURE 23



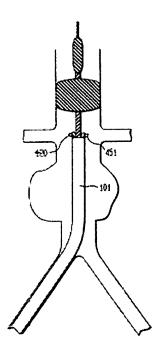


FIGURE 33

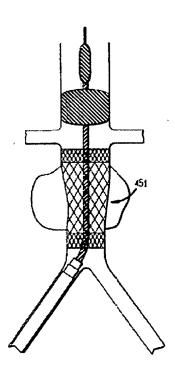
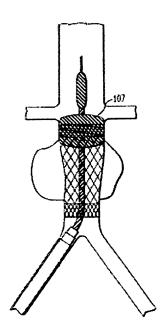
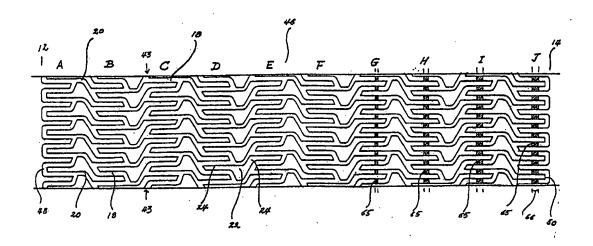


FIGURE 34



## **THE JANG '484 APPLICATION**

## FIGURE 8



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